DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95097d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-05-10

November 19, 2004

Raul Interian, President
Jomara Seafood, Inc.
2275 West 9th Avenue
Hialeah, Florida 33010-2001

Dear Mr. Interian:

On July 8-9, 2004, the Food and Drug Administration (FDA) conducted an inspection of your facility located at the above address. The inspection was conducted to determine your firm's compliance with FDA's seafood Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR Part 123). The seafood HACCP regulations were issued pursuant to Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Seafood that is processed in violation of the HACCP regulations is adulterated, according to the Act, because it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's homepage at http:// www.fda.gov.

During our inspection, the FDA investigator provided you with the form FDA 483, which presents her evaluation of your firm's performance regarding various aspects of the HACCP requirements. The FDA investigator observed deviations by your firm from the special requirements for imported products (21 CFR 123.12). The observations of concern to us are as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for the frozen Tilapia and frozen shrimp imported from China.

2. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for frozen Tilapia manufactured by [redacted] in China and frozen shrimp manufactured by [redacted] in China.

The above identified deviations are not intended to be an all inclusive list of the deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and applicable federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, the FDA may detain your imported seafood products without examination. Under such conditions, the FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state your reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding the implementation of the seafood HACCP regulations, you may contact Ms. Englund at (407) 475-4741, for answers and/or directions toward guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP plan.

Sincerely,

for Emma R. Singleton
Director, Florida District